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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

CENTER FOR ENVIRONMENTAL HEALTH, et al.,

Plaintiffs,

v.

ANDREW WHEELER, in his official capacity as Administrator of the U.S. Environmental Protection Agency, et al.,

Defendants.

CASE NO. 4:18-cv-03197-SBA

REPLY MEMORANDUM IN SUPPORT OF MOTION TO DISMISS SECOND AMENDED COMPLAINT

Date: June 12, 2019
Time: 2:00 p.m.
Location: Oakland Courthouse, 1300 Clay Street, Courtroom 210, 2nd Floor

List of Exhibits to Federal Defendants' Reply Memorandum

Exhibit	Description
Q	Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes (Mar. 19, 2013)

I. INTRODUCTION

In their Response to Defendants' Motion to Dismiss (ECF 54) ("Pl. Br."), Plaintiffs rely on tenuous assertions of potential harm to their members to support their alleged standing and wrongly assail the Environmental Protection Agency ("EPA") and the U.S. Fish and Wildlife Service ("FWS") on the grounds that the agencies have failed to engage in consultation under Section 7 of the Endangered Species Act ("ESA"). Plaintiffs make these allegations even though they know that EPA initiated consultation with FWS in January 2017, and that the consultation is ongoing, with FWS having obtained a lawful extension of the consultation period as provided in ESA Section 7(b)(1). Plaintiffs have not cured their lack of standing, demonstrated that the Court has subject matter jurisdiction over the alleged violations of Section 706(2) of the Administrative Procedure Act ("APA"), or established that the Second Amended Complaint ("Complaint") states a claim for relief based on alleged violations of APA Section 706(1). Finally, Plaintiffs' claim that FWS and EPA have committed procedural violations of ESA Section 7(a)(2) is moot because the agencies have met or are meeting their procedural obligations.

II. ARGUMENT

A. Plaintiffs Fail To Plead Facts Sufficient To Show Standing.

1. Plaintiffs' arguments regarding harm and redressability are flawed.

To satisfy Article III's requirement of a "case or controversy," a plaintiff must establish standing by showing "(1) an injury in fact that (2) is fairly traceable to the challenged conduct and (3) has some likelihood of redressability." *Jewel v. Nat'l Sec. Agency*, 673 F.3d 902, 908 (9th Cir. 2011) (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992)); *see Ctr. for Biological Diversity v. EPA*, 316 F. Supp. 3d 1156, 1164 (N.D. Cal. 2018). Even at the pleading stage, Plaintiffs must allege that their members have cognizable interests in species that may be affected by products containing malathion. *Ctr. for Biological Diversity*, 316 F. Supp. 3d at 1165. Here, Plaintiffs have presented affidavits from members of the Center for Biological Diversity ("CBD") about numerous species, expressing concern about pesticides, ECF 54-2, 54-4 ("Burd Decl."), 54-5, 54-8, 54-9, 54-10, but standing in this case requires more than just generalized concerns about "pesticides" when the Complaint itself rests on allegations

concerning 21 specific malathion-containing products. In other words, Plaintiffs' declarations fail to allege harm to their interests in the listed species of concern that is "fairly traceable" to the registration actions for the 21 products listed in the Complaint. Even if, as Plaintiffs contend, they are not required "to identify precise geographic areas a product is used in," Pl. Br. at 6 (citing *Ellis v. Housenger*, 252 F. Supp. 3d 800 (N.D. Cal. 2017)), they offer the Court no factual assertions about any particular malathion product that would allegedly be applied in the areas pertinent to the species, or even that any of the 21 products named in the Complaint could be used in those areas. *Whitmore v. Arkansas*, 495 U.S. 149, 155-56 (1990) ("[a] federal court is powerless to create its own jurisdiction by embellishing otherwise deficient allegations of standing"). The Supreme Court has explained that "Rule 8 does not empower respondent to plead the bare elements of his cause of action, affix the label 'general allegation,' and expect his complaint to survive a motion to dismiss." *Ashcroft v. Iqbal*, 556 U.S. 662, 687 (2009). The Complaint must include enough "factual enhancement [to cross] the line between possibility and plausibility." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007) (citation omitted). And, while Plaintiffs characterize their claims as "based on EPA's failure to complete consultation on pesticide product registrations," Pl. Br. at 6, the Complaint reveals that their claims are much narrower and rely on EPA's actions regarding just 21 products.

As to the two manufacturing use products listed in the Complaint (Malathion 96.5% (EPA Reg. No. 19713-402) and Fyfanon Technical (EPA Reg. No. 4787-5)), although Plaintiffs do not dispute that they are used only in factories to produce the pesticide products that will be used by growers and others, they nevertheless claim that these manufacturing use products are registered "for the purpose of being the direct source of malathion that is used in the environment." Pl. Br. at 9. Plaintiffs seem to be arguing that, even if those two specific products are themselves never used in a manner such that listed species are exposed to them, nor used in listed species' critical habitat, they have standing nonetheless to assert claims about them. *See id.* While the ESA requires an analysis of direct and indirect effects of agency action, Plaintiffs' argument stretches the chain of causation beyond its logical breaking point. Plaintiffs offer no explanation of how those two products (as opposed to end-use products which are ultimately

made from them) injure their recreational or aesthetic interests.

Similarly, in arguing that their claims are redressable, Plaintiffs rely on the Court's inherent power to fashion relief, Pl. Br. at 12, and further argue that the ongoing consultation concerns all pesticide products that contain malathion. But asking the Court to order completion of the ongoing consultation (a request that has its own defects, *see* Section II.B, *infra*) is a much different remedy than asking the Court to issue a broad vacatur of registration actions for all pesticide products containing malathion when the Complaint concerns just 21 specific products. *Nat. Res. Def. Council v. Winter*, 508 F.3d 885, 886-87 (9th Cir. 2007) (injunctive relief must be narrowly tailored to the specific harm alleged); *see* ECF 43 (Compl., Prayer for Relief, ¶ 5). Plaintiffs do not dispute that the original registration actions for most products containing malathion occurred years ago or that the statute of limitations on EPA's action with respect to many of those products has expired. ECF 51 ("Fed. Defs. Br.") at 8. The registration actions for such products are outside of the scope of the Complaint and therefore beyond the Court's reach. Indeed, as previously explained, the vacatur of EPA's product reregistration decisions would not take products off the market or compel completion of consultation; it would simply reinstate the terms of the original registration decisions which Plaintiffs are time-barred from challenging. Thus, any vacatur of the challenged reregistration decisions would address only those decisions, leaving the relevant registrations in place while EPA makes new reregistration decisions for those 18 products. Fed. Defs. Br. at 8-9. Moreover, the vacatur would have no effect on reregistration or registration decisions for dozens of other malathion-containing products, as the Complaint addresses only a fraction of all approved malathion products. For these reasons, Plaintiffs' requested relief will not redress their alleged injury.

2. Plaintiffs fail to cure the defects in their allegations of organizational standing.

Federal Defendants previously identified significant defects in Plaintiffs' allegations of organizational standing. Fed. Defs. Br. at 9-10. In response, Plaintiffs[1] contend that their

[1] The Center for Biological Diversity was the only one of the three Plaintiffs to submit declarations on the issue of organizational standing.

organizational missions have been frustrated and resources have been "diverted from other organization priorities." Pl. Br. at 10. Here, the declarations submitted by CBD are replete with references to concerns about the effect of "pesticides, including malathion. . . [on] the health of wildlife and plant life," Burd Decl. ¶ 11, and the organization's efforts to obtain information through Freedom of Information Act requests about "the government's failure to complete Section 7 Consultations regarding pesticides." *Id.* ¶ 14. CBD also describes the preparation of a report in 2006 that "examined the risk that toxic pesticides, including malathion, pose to endangered species in the nine Bay Area counties." *Id.* ¶ 22. But the work that the CBD declarants describe reflects work done because of the alleged "failure to comply with the ESA when registering pesticides," *id.* ¶ 16 (emphasis added), rather than EPA's alleged failure to comply with the ESA when taking actions specifically related to malathion. This defect is repeated over and over again. *E.g.*, Burd Decl. ¶¶ 25, 28, 33; ECF 54-7 ("Hartl Decl.") ¶¶ 5, 7, 9 11.[2] Thus, the fatal flaw in Plaintiffs' evidence is that, while CBD alleges it is heavily invested in issue advocacy related to pesticides, it has not shown that any advocacy regarding malathion has forced it to divert resources from its already-concerted efforts.

In short, Plaintiffs must allege the agencies' actions caused them to expend additional resources and that, "but for" those actions, they would have used those resources to accomplish other aspects of their organizational mission. *See Nat'l Council of La Raza v. Cegavske*, 800 F.3d 1032, 1040-41 (9th Cir. 2015). This they have failed to do. The facts provided by Plaintiffs demonstrate only that CBD has taken actions that are consistent with the organization's advocacy mission. *See* https://www.biologicaldiversity.org/programs/environmental_health/ (last visited Apr. 18, 2019). Where the alleged harm is merely a setback to an organization's abstract social interests rather than a concrete and demonstrable injury to the organization's resources, the injury in fact requirement has not been met. *See Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982); *see also Sierra Club v. Morton*, 405 U.S. 727, 734-35 (1972) (no organizational

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[2] CBD briefly describes involvement in EPA's preparation of its biological evaluation related to malathion, but that is the very document that served to initiate the consultation at issue here. Burd Decl. ¶ 27.

standing where an organization alleges merely a special interest in a problem); *Ctr. for Biological Diversity v. Zinke*, No. 17-cv-2504-RCL, 2019 WL 1430222, at *14 (D.D.C. Mar. 29, 2019) (organization failed to establish standing where it relied on increased expenditures that "relate directly and exclusively to pure issue-advocacy").

B. Plaintiffs' Claims Regarding Alleged ESA Procedural Obligations Are Moot.

The First Claim of the Complaint alleges that EPA and FWS violated their procedural duties under ESA Section 7(a)(2). As previously explained, this claim is moot because EPA has complied with its procedural obligations and FWS is in the process of preparing the biological opinion that is the subject of this lawsuit. Fed. Def. Br. at 14-15. Therefore, there is no effective relief that can be granted as to either agency.

In response, Plaintiffs argue that the Court "can issue an order requiring completion of consultation by a reasonable date certain" and vacate EPA's registrations of pesticide products containing malathion until consultation is complete. Pl. Br. at 24. But this argument misses the mark. Plaintiffs have not identified a single additional step that ESA Section 7(a)(2) requires EPA to take, nor can they. As the action agency, EPA's procedural responsibilities under ESA Section 7(a)(2) were complete when it requested initiation of consultation in January 2017, and submitted its biological evaluation to FWS. Indeed, Plaintiffs do not dispute this point. Instead, they attempt to conflate the separate procedural and substantive duties under ESA Section 7(a)(2) by contending that EPA's "procedural duty is not satisfied until the consultation is complete." Pl. Br. at 23; *see also id.* at 17 (stating that EPA is "required to complete consultation"). Plaintiffs do not cite any legal authority for this proposition, nor are Federal Defendants aware of any legal support for this argument as it relates to an action agency.[3] Plaintiffs further contend that "EPA has been complicit in failing to complete consultation by

[3] EPA also has a substantive duty under ESA Section 7(a)(2) to avoid jeopardy. 16 U.S.C. § 1536(a)(2). The First Claim of the Complaint asserts a cause of action on this ground against EPA. Compl., ¶¶ 90-96. While Plaintiffs have failed to demonstrate standing for any of their claims, Federal Defendants have not otherwise moved to dismiss that aspect of the First Claim, nor the Third Claim of the Complaint, which asserts a claim under ESA Section 7(d).

agreeing to extend consultation." *Id.* at 23. But this is Plaintiffs' characterization, not a cause of action, and their argument has no basis because the ESA specifically allows an action agency to consent to a request to extend consultation. 16 U.S.C. § 1536(b)(1). Plaintiffs provide no legal authority to the contrary.

As to FWS, it is in the process of preparing its biological opinion. It has provided estimated dates of completion of a draft biological opinion (April 2020) and a final biological opinion (March 2021). Plaintiffs' insistence that the procedural claims against FWS are not moot rests on the faulty premise that the Court should order FWS to complete a statutory task that it is already engaged in. Such an order would be wholly ineffective in light of the agency's ongoing work. Indeed, Plaintiffs fail to address Federal Defendants' argument that other courts have found the same type of claims to be moot where the action agency has initiated consultation. *See* Fed. Defs. Br. 15 (citing *Am. Littoral Soc'y v. EPA*, 199 F. Supp. 2d 217, 245-47 (D.N.J. 2002) (failure-to-consult claim was moot where agency had sent letters seeking consultation because no further effectual relief could be granted); *Sw. Ctr. for Biological Diversity v. U.S. Forest Serv.*, 82 F. Supp. 2d 1070, 1079 (D. Ariz. 2000) (failure-to-consult claim was moot where agencies had begun consultation, and noting the "settled rule against issuing advisory opinions")).

Plaintiffs rely on several cases to urge the Court that it has jurisdiction to require consultation to be completed by a date certain, even though the consultation is ongoing. Each of their cases misses the mark. In two of the cited cases, consultation had not yet been initiated, thus giving the courts reason to issue such an order. *E.g.*, *Wash. Toxics Coal. v. EPA*, 2002 WL 34213031, at *10 (W.D. Wash. July 2, 2002); *Pac. Coast Fed'n of Fishermen's Ass'ns v. U.S. Bureau of Reclamation*, 138 F. Supp. 2d 1228, 1244 (N.D. Cal. 2001) (the action agency "never formally consulted with [the consulting agency] concerning this [operations] plan"). In the third cited case, the court rejected a mootness argument based on an intervening event that was outside of the action agency's control, which is not an argument Federal Defendants make here. *E.g.*, *Nw. Envtl. Def. Ctr. v. Gordon*, 849 F.2d 1241 (9th Cir. 1988). To the contrary, Federal Defendants are arguing that the First Claim is moot because EPA has completed the steps necessary to satisfy its ESA Section 7 procedural duties, and FWS is in the process of

completing its ESA Section 7 procedural duties, which is the exact relief requested by Plaintiffs.

C. Plaintiffs' APA Claims Should Be Dismissed.

Plaintiffs' claim that the extension of consultation violates the APA should be dismissed because it fails to state a claim for which relief can be granted under APA Section 706(1) and fails to allege final agency action under APA Section 706(2).

1. Plaintiffs fail to state a claim for "unlawful withholding or unreasonable delay."

Plaintiffs argue that extension of the consultation period constitutes unlawful withholding or unreasonable delay of agency action in violation of APA Section 706(1). To establish a right of review under APA Section 706(1), a plaintiff must assert "that an agency failed to take a *discrete* agency action that it is *required to take*." *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 64 (2004); *see Ecology Ctr. v. U.S. Forest Serv.*, 192 F.3d 922, 926 (9th Cir. 1999) (a plaintiff must sufficiently allege a failure to perform a mandatory duty and cannot attempt "to evade the finality requirement with complaints about the sufficiency of agency action 'dressed up as an agency's failure to act.'" (quoting *Nevada v. Watkins*, 939 F.2d 710, 714 n.11 (9th Cir. 1991)). A court's "ability to 'compel agency action' is carefully circumscribed to situations where an agency has ignored a specific legislative command." *Hells Canyon Preservation Council v U.S. Forest Serv.*, 593 F.3d 923, 932 (9th Cir. 2010). Here, Plaintiffs are complaining about the reasons for the extension of the consultation, as they cannot complain that either agency "has ignored a specific legislative command." *Id.*

ESA Section 7(b)(1) establishes the timelines for the consultation process, and further provides that the timelines may be extended if both the action agency and any applicants consent. That is exactly what happened here. *See* Fed. Defs. Br. at 3-5. FWS complied with the provisions of ESA Section 7(b)(1), which require that a request for extension be in writing, and set forth the reasons why a longer period is required, the information that is required to complete the consultation, and the estimated date on which the consultation will be completed. 50 C.F.R. § 402.14(e). Consistent with its obligation to "alert the Federal agency and any applicant of areas where additional data would provide a better information base from which to formulate a biological opinion," 51 Fed. Reg. 19,926, 19,951-52 (June 3, 1986), FWS explained why a

longer period is required and the information that is required to complete the consultation. Fed. Defs. Br., Ex. C, H-J. Consultations that extend beyond the statutory time periods are neither unusual nor outside the bounds of the law: "Congress expressly contemplated that FWS might need more than 90 days to conduct a review and provided a mechanism for it to do so." *Sierra Club v. U.S. Dep't of Interior*, 899 F.3d 260, 273 (4th Cir. 2018).[4] In light of this recognition, this Court should not involve itself in the conduct of complex consultations, particularly when the consulting agency complied with the plain terms of the ESA.

Notwithstanding FWS's compliance with ESA Section 7(b)(1), Plaintiffs nonetheless insist that the Court should allow their unreasonable delay claim to go forward. Pl. Br. at 17. While they dispute that they are trying to micromanage FWS's processes, *id.* at 18, that statement cannot be squared with the fact that, although FWS has explained why it needs more time to complete the consultation, Plaintiffs have sued anyway because consultation has not been completed on the timeframe that Plaintiffs demand. Similarly unavailing is Plaintiffs' argument that they have stated a cognizable claim for unreasonable delay because, before FWS issued its extension request, the agency had "determined that authorized uses of malathion . . . are likely to jeopardize the continued existence of species that are supposed to be protected by the ESA." Pl. Br. at 16, 18. This argument is not accurate, as FWS has not issued a draft biological opinion, much less a final biological opinion. Fed. Defs. Br., Ex. P ¶¶ 4, 9. Plaintiffs also seem to contend that, once the agencies appeared to settle on a path in the deliberative process for analyzing the data and making a determination of direct and indirect effects, they were locked into that methodology and not allowed to change it before completing consultation. There is no legal support for that argument, as "[j]udicial review of agency action should be based on an agency's stated justifications, not the predecisional process that led up to the final, articulated decision."

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[4] Notably, in requesting an extension, the ESA requires only that the consulting agency provide an "estimated date on which consultation will be completed,"16 U.S.C. § 1536(b)(1)(B)(i)(III) (emphasis added), which itself demonstrates that Plaintiffs' unreasonable delay claim should be dismissed. *See also* 50 C.F.R. § 402.14(e)(3).

Ad Hoc Metals Coal. v. Whitman, 227 F. Supp. 2d 134, 143 (D.D.C. 2002); *see also Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 658-59 (2007).

Finally, Plaintiffs contend that the ESA's consultation timeframes do not preclude review of their claims under the APA. In other words, according to Plaintiffs, the fact that FWS complied with the statutory requirements of ESA Section 7(b)(1) and EPA exercised its vested discretion to agree to the extension request, is not dispositive. Pl. Br. at 18. But Plaintiffs' attempt to characterize Federal Defendants' position as one that argues that the agencies "could delay completion of consultation for fifty years to count the number of insects left in the United States," *id.* at 19, is hyperbole that is inapposite to the present case. *See* Ex. C, H-J, P. Federal Defendants complied with ESA Section 7(b)(1) when FWS requested an extension of the consultation period in writing, and stated the reasons why a longer period is required, the information that is required to complete the consultation, and the estimated date on which the consultation will be completed. EPA had discretion to consent to FWS's statutorily compliant request. These facts cannot support an unreasonable delay claim. To the extent that Plaintiffs believe their interests have been harmed during the pendency of the consultation, they can seek a remedy under ESA Sections 7(a)(2) and 7(d) (and have done so), but cannot direct the length and substance of the interagency consultation process. The Court should reject Plaintiffs' efforts to make an end-run around the ESA and dismiss their APA Section 706(1) claim.

2. Extension of the consultation is not final agency action.

Plaintiffs argue that the extension of consultation is reviewable under APA Section 706(2) because the extension itself constitutes final agency action. Pl. Br. at 21-23. To obtain judicial review under APA Section 706(2)(A), a plaintiff must establish that the activity at issue is "final agency action." *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 882 (1990). The action "must not be of a merely tentative or interlocutory nature." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997). For an agency action to be considered final under the APA: (1) the action "must mark the consummation of the agency's decisionmaking process," and (2) it "must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Id.* at 177-78 (internal citations and quotation marks omitted). These criteria are missing here.

Plaintiffs argue that the decision to extend the consultation period is not an intermediate step in a multi-stage administrative process and that "ESA consultations typically do not have multiple steps." Pl. Br. at 22. This characterization of the ESA Section 7 process ignores that there are other steps in the consultation process, such as the consulting agency's provision of a draft of the biological opinion to the action agency, an intermediate step explicitly anticipated for this consultation, together with a notice and comment period, which is not generally part of typical ESA consultations. *See* Ex. A; Ex. Q at 11. Were the Court to adopt Plaintiffs' view of the extension of consultation as "final agency action," outside parties could seek to interject themselves by second-guessing each and every decision in the ESA Section 7 process – a result that plainly is not contemplated by the APA nor the ESA.

Relying on *Navajo Nation v. U.S. Department of Interior*, 819 F.3d 1084 (9th Cir. 2016), Plaintiffs argue that the extension of consultation marks the consummation of agency decisionmaking regarding that issue. Pl. Br. at 22. But *Navajo Nation* is plainly distinguishable, as the court found reviewable "final agency action" in that case, where the federal agency decided to apply a specific statute to Native American remains, which immediately determined the plaintiffs' legal interests, and had legal consequences. 819 F.3d at 1091. Further, the agency's decision constituted its exercise of jurisdiction and legal authority over the plaintiffs, contrary to their claim of right. *Id.* Here, however, in the ESA Section 7 context, the issuance of a biological opinion and an accompanying incidental take statement are considered the final agency actions. *Bennett*, 520 U.S. at 178; *Ariz. Cattle Growers' Ass'n v. U.S. Fish & Wildlife Serv.*, 273 F.3d 1229, 1235 (9th Cir. 2001). Thus, the extension of the consultation literally extended the timeframe to make an actual, substantive decision in the future, without determining any outside party's legal interests, and cannot be construed as final agency action. *Ukiah Valley Med. Ctr. v. FTC*, 911 F.2d 261, 263-64 (9th Cir. 1990); *Hecla Mining Co. v. EPA*, 12 F.3d 164, 166 (9th Cir. 1993) (no final agency action where agency simply took a preliminary step in statutory process).

III. CONCLUSION

For all these reasons, the Court should dismiss the Second Amended Complaint.

Dated: April 19, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 19, 2019, I electronically filed the foregoing with the Clerk of the Court via the CM/ECF system, which will send notification of such to the attorneys of record.

/s/ Alison C. Finnegan

Exhibit Q

March 19, 2013

ENVIRONMENTAL PROTECTION AGENCY
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs

Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives

Purpose of this Document:

This document, which was developed jointly by the EPA, the U.S. Department of Agriculture (USDA), the National Marine Fisheries Service (NMFS) in the U.S. Department of Commerce and the Fish and Wildlife Service (USFWS) in the U.S. Department of Interior[1], provides guidance to staff and managers participating in the associated processes. It does not create or confer legal rights or impose any legally binding requirements on the agencies or any other party.

Table of Contents:

[1] NMFS and USFWS are referred to collectively as the Services.

1 Introduction

This document pertains to Federal agency implementation of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)[2] and the Endangered Species Act (ESA)[3]. This document describes how the agencies will implement the statutes in the context of pesticide registration review decisions. In August 2012, EPA published a draft proposal and solicited public comments for 60 days. EPA, USDA, and the Services subsequently revised the document after consideration of the public comments received.

The process of assessing the potential effects of a pesticide to federally listed threatened and endangered species (hereafter referred to as listed species), determining whether risk reduction measures are necessary to ensure these species are not likely to be jeopardized and critical habitat is not destroyed or adversely modified, and implementing such measures requires close coordination across multiple Federal agencies and impacts a variety of entities including state pesticide regulatory agencies, pesticide users and pesticide companies. The process of ensuring protection of these species is one that will benefit from input by these entities as well as the general public. There are multiple opportunities for soliciting and considering such input at various points in the process as noted below. Because stakeholders, including state governments, universities, and growers/users have significant amounts of relevant information and are the ultimate implementers of pesticide labels in the field, it is critical that they have a seat at the table during the development of any needed risk reduction measures to ensure that such measures are technologically and economically feasible.

Over the past several years, stakeholder groups have increasingly expressed interest in ESA issues involving pesticide registration. Furthermore, Congressional committees have also stressed the importance of an open and transparent process ensuring that at multiple stages of the process there are opportunities for broader public participation and that the economic impacts on agriculture are more fully integrated into the process before a final decision is made. This paper describes how the Federal agencies can clarify and/or modify their processes to address these concerns and increase the robustness of the overall process. This paper specifically describes changes to EPA's registration review process and the Services' Section 7 consultation process that are intended to facilitate ESA pesticide consultations and coordination across these Federal agencies. In addition, it calls for a greater role for USDA.

These process changes recognize and acknowledge the respective expertise of the four agencies involved. USDA's expertise on crop distribution and their relationships with the agricultural community are critical links between EPA's expertise on pesticides and the Services' expertise on listed species' locations, status, and biology. Each agency's expertise defines their respective roles and responsibilities during consultation.

2 EPA's Registration Review Program

The Food Quality Protection Act (FQPA) of 1996 amended FIFRA to include a mandate that EPA establish a new program[4], called registration review[5], so that, as the ability to assess risk evolves

[2] 7 U.S.C. 136a *et seq.* (http://www.epa.gov/lawsregs/laws/fifra.html).
[3] 16 U.S.C. §1531 *et seq.* (http://www.epa.gov/lawsregs/laws/esa.html).
[4] FIFRA Section 3(g), 7 U.S.C. 136a(g).
[5] For more information about EPA's registration review program, go to http://www.epa.gov/oppsrrd1/registration_review/.

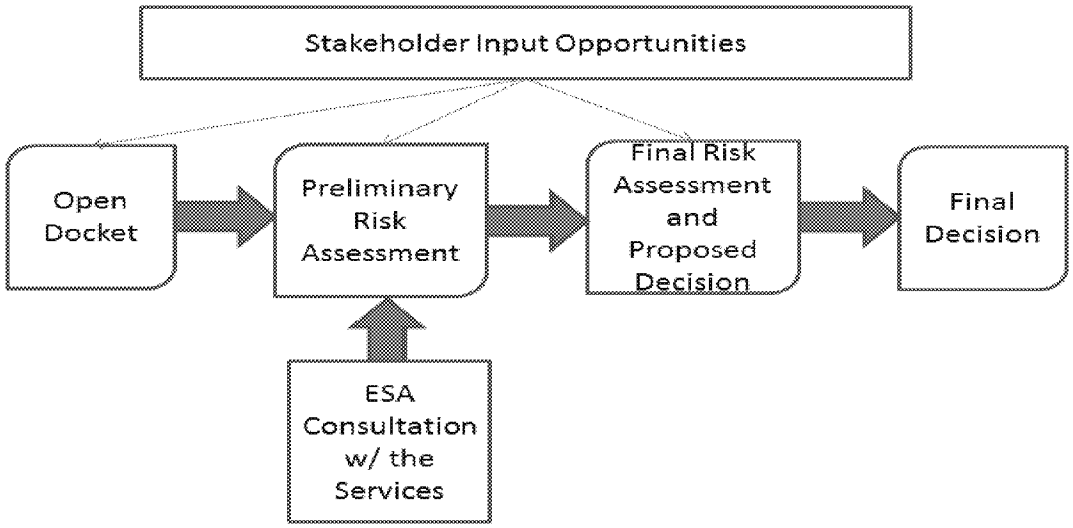
and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health and the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, EPA periodically reevaluates pesticides to ensure that as change occurs, products in the marketplace can still be used safely. The registration review program challenges EPA to continuously improve its processes, science, and information management while maintaining a collaborative and open process for decision-making. In general, EPA intends to accomplish its work relative to protection of listed species in the course of its registration review program. That work will include, where appropriate, consultation with the Services.

Under EPA's regulations, the registration review program is a multi-stage process, incorporating opportunities for public comment at critical points in the review process. As originally designed, interested stakeholders can comment on and provide relevant information at three critical points during the registration review process: the initial docket opening, the preliminary risk assessment, and the proposed decision. These points in the process are publically announced and accompanied by time frames and deadlines for the submission of comments and relevant information.

At the stage where EPA opens the registration review docket, the Agency issues a preliminary work plan and invites the public to provide feedback on how EPA will scope the review (i.e., problem formulation) and what data will be required as part of this review. Following the completion of the public comment period, EPA reviews the information submitted, develops a response to comments document, and issues a final work plan. After the required data have been submitted and evaluated, EPA develops a preliminary risk assessment that addresses potential human health and ecological exposures and issues that scientific analysis for public comment.[6] EPA's ecological risk assessments will become a "biological evaluation" during consultation with the Services. After reviewing public comments, EPA revises the risk assessment, as needed, develops a response to comments document, proposes risk reduction measures it believes are necessary to address risk concerns, and invites the public to provide feedback on its proposed decision. It is only after these multiple stages of public comment that the Agency issues its final registration review decision. Figure 1 provides an overview of the original registration review program.

[6] When originally designing the registration review program, EPA intended to initiate consultation with the Services (if needed) at the point in the registration review process where comments were being sought on the preliminary risk assessment. The concept was that while the Agency was soliciting public input on the preliminary assessment, EPA would also engage in consultation with the Services, resulting in a Biological Opinion that could be incorporated into a final risk assessment and proposed registration review decision at the next step in the process.

Figure 1. Original Design of EPA's Registration Review Program



Over the past year, EPA has engaged in significant dialogue with the Services and other stakeholders regarding how to improve the registration review process. At a summary level, most stakeholder groups have recommended that EPA make changes to its process to accomplish several goals: 1) earlier stakeholder involvement in the scoping of the pesticide's re-evaluation, 2) earlier adoption of risk reduction measures, including incorporation of clarifications and/or new restrictions on product labels, before initiation of any needed consultations with the Services and prior to completion of the registration review, and 3) a more focused consultation process (when and if necessary) that reflects the adoption of such measures.

3 Process Improvement Discussions

In May 2011, the Minor Crop Farmer Alliance (MCFA) convened a workshop in Denver, Colorado, with three primary goals:

- Provide grower representatives with an understanding of the processes and analyses leading to the identification of risk and risk reduction options by EPA and by the Services.
- Identify grower-level data that could potentially refine the risk assessment and enhance the risk identification and risk reduction decision processes.
- Initiate discussions on the mechanisms for providing such data.

Several questions emerged from these discussions and have served to inform potential improvements to the registration review and consultation processes:

- What are the appropriate points in the registration review process to initiate discussions with both the registrant and the user community to identify, describe and verify crop specific use and usage information?

- What data sources are most complete and relevant to the risk assessment process?

- How will commodity groups know when to engage in the process?

- How will the agencies ensure that information collected and submitted is considered?

Subsequent to the workshop, EPA solicited input from its Federal advisory committee, the Pesticide Program Dialogue Committee (PPDC), regarding potential process changes that would facilitate greater opportunities for public participation and transparency in the registration review process and have the additional benefit of streamlining ESA consultation with the Services.

After considering public feedback based on the August 2012 proposal, and advice from the PPDC, EPA has implemented changes to the registration review process further augmenting opportunities for public involvement in the process. These changes are described below.

Earlier involvement of stakeholders in the Registration Review Process

As part of the registration review process, EPA annually publishes a four-year schedule to communicate when individual pesticides will enter the registration review program. To enhance transparency in the process, EPA has begun including information on the specific timeframe within any fiscal year when a pesticide will begin its review. Having this information available in advance provides early notice for interested stakeholders to submit information to EPA in advance of the pesticide beginning its re-evaluation[7].

During FY12, EPA began holding "Focus" meetings during the early stage of registration review. EPA believes that these meetings increase efficiency and help to better inform the problem formulation and risk assessment phases of the registration review process. EPA uses "Focus" meetings to begin initial outreach efforts to stakeholders. A "Focus" meeting is initiated by EPA with affected registrants and possibly other stakeholders via invitation[8]. EPA will extend invitations to USDA, and, where applicable, to the Services, to attend "Focus" meetings. The USDA can help identify affected growers and ensure they are aware of time frames for registration review. The Services can respond to questions and concerns regarding any existing ESA issues, such as, ongoing litigation.

In an effort to create a transparent process and broaden stake holder participation, EPA will place the "Focus" meeting minutes and related materials (the invitation letter, a sign-in sheet containing contact information for the meeting attendees, documents provided by the EPA, registrants, or other attendees, and any other related material) in the publically-available,

[7] For more on registration review schedules go to http://www.epa.gov/oppsrrd1/registration_review/schedule.htm
[8] For more details on "Focus" meetings visit: http://www.epa.gov/oppsrrd1/registration_review/focus-meetings.html

chemical-specific registration review dockets within 45 days[9], but will strive to have those materials posted to the docket within 10 business days of the meeting. Additional follow-up meetings and calls will be held as needed. If upon reviewing the minutes and materials of the meeting, an interested stakeholder wishes to meet with EPA and discuss these issues, they can contact EPA and request a meeting. Contact information for EPA will be included in the chemical-specific docket materials. EPA can initiate discussions with registrants and other parties at any point in the registration review process.

Similar to the "SMART" meetings that were held during reregistration, these "Focus" meetings provide the registrants and other interested stakeholders opportunities to: 1) identify the uses that the registrant intends to support for registration review, 2) address label language that is vague, insufficient, or inaccurate at an early stage of the review process, and 3) adopt risk reduction measures before registration review begins.

Purpose #1: Define the use patterns supported by the registrants. Markets and the economic viability of certain pesticide uses change over time. Through the "Focus" meetings, EPA will ask the manufacturers to explicitly indicate which uses they intend to continue to support for registration. This provides an opportunity to begin the process of defining the scope of the Federal action to be considered under the ESA.

Purpose #2: Ensure label language accurately reflects product use and usage. Inaccuracies, missing information, and vague or poorly worded label language should be identified. Confusion regarding label directions will be addressed at this stage in the process so that the risk assessment more accurately reflects the intended use of the pesticide. One such example is inclusion of specificity on the maximum number and frequency of applications. Products and use patterns can be discussed to maximize the potential for species' protections while maintaining a critical use. When applicable, EPA will follow-up with additional meetings with state regulators, USDA, and commodity groups on proposed use site/label changes.

Purpose #3: Identify potential risk drivers and potential risk reduction measures as early as possible. Previous risk assessments, conducted either to support reregistration decisions, new uses, or litigation, may have indicated potential ecological risks. Alternative chemicals may have been developed since those initial evaluations; as a result, the benefits of the pesticide beginning registration review may have changed. There may also be the potential, based upon further field experience with the pesticide, to identify the key efficacious rates critical for crop protection and/or existing conservation practices being employed that could be incorporated into labels as part of "early risk reduction."

It is a common goal of the Federal agencies to have accurate use and usage language on product labels, and, when possible, agreed upon risk reduction measures incorporated onto product labels before the pesticide reaches the preliminary risk assessment stage. This saves valuable resources for all.

[9] Under the registration review rule (40 CFR 155.52), the EPA has 45 days to docket meeting minutes and related materials. A special Focus Meetings docket has been established for meeting material; visit EPA-HQ-OPP-2012-0778 at www.regulations.gov.

Consideration of pesticide use and usage data

During a two to three-year period of time after completion of the final workplan, the registrant is often developing toxicity and exposure data to support the preliminary risk assessment for the pesticide's registration review. As this information is being submitted to EPA, updated use data (i.e., data identifying registered use sites) and usage information (i.e., information explaining how products are applied to specific use sites) will be solicited from a variety of sources, including USDA and grower organizations. These data, such as application methods, application rates, frequency of application, and application timing are critical pieces of information in developing EPA's ecological risk assessment. For example, having more complete information on the times of the year when a pesticide is used may enable EPA to more accurately predict the potential exposure of listed species to pesticides.

EPA will incorporate these data, which may be national and/or local in scope, to refine the label and/or identify typical use rates for risk characterization, to define the uses that will be supported for registration review, and to facilitate the potential adoption of any additional needed risk reduction measures with the possibility of reducing, or eliminating the number of "may affect, likely to adversely affect" determinations under the ESA. These data can also be used to describe the situations in which rates higher than "typical" rates are needed and under what conditions, allowing more prescriptive label language to be developed. Ultimately, these data should result in a refined preliminary (ecological) risk assessment.

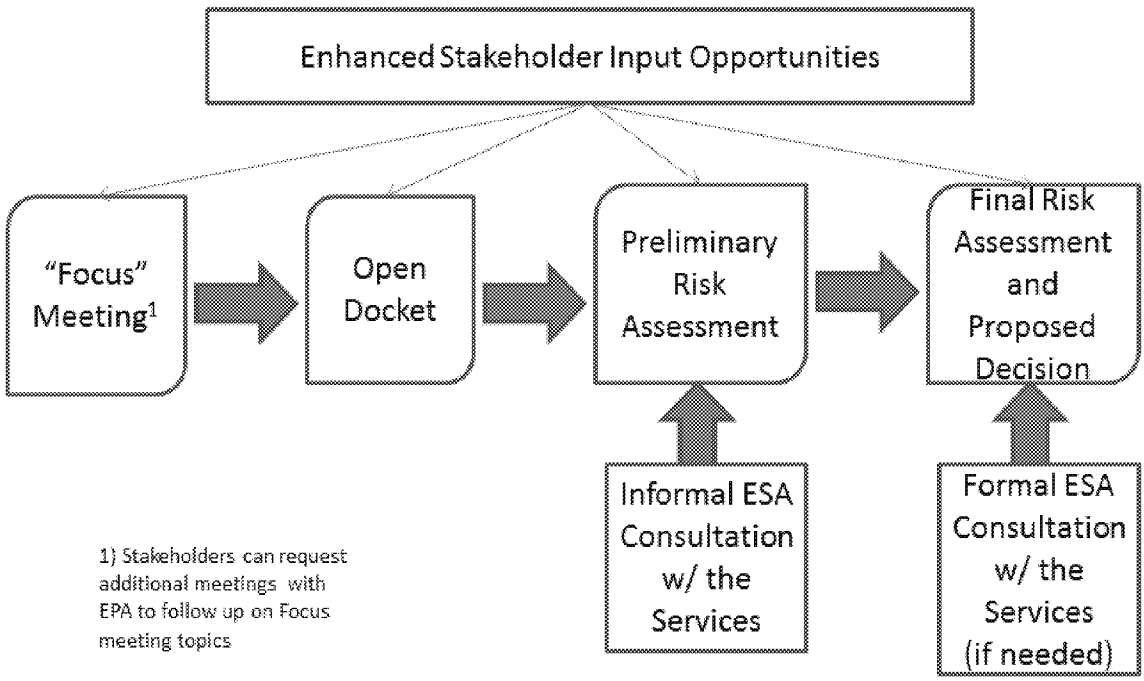
EPA has a long history of using these data in making pesticide safety determinations. For example, pesticide usage data collected by USDA's National Agricultural Statistics Service (NASS) have been found to be of exceptional quality and reliability in making food safety determinations (i.e., "reasonable certainty of no harm" determinations) under the FQPA. Congress has directed EPA to use data, such as those developed by NASS when EPA "finds that the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue," provided that the Agency periodically reevaluates the estimate of the anticipated exposure in light of these data.

Increased use of the informal (or early) consultation process

A critical step in developing the preliminary ecological risk assessment is having reliable data on species habitat, diet, geographic range, and behavior. EPA will use the informal consultation process to work with the appropriate Service to gather this information for inclusion in a more refined ecological risk assessment. Collaborating with the Services to gather this information at an earlier stage in the process has a number of benefits, including 1) incorporation of more refined species biology and habitat information into EPA's effects determinations, 2) potential reduction in the number of "may affect, likely to adversely affect" determinations, and 3) fewer resources (for both EPA and the Services) needed to complete consultations because the best available information has been incorporated into EPA's preliminary ecological risk assessment. Early interaction under informal consultation will allow EPA and the Services to identify potential risk to listed species and their habitats and would position EPA to begin discussing potential risk reduction measures with the pesticide registrant. Even when this informal consultation does not eliminate the need for formal consultation, the work accomplished through informal consultation will inform and streamline the formal consultation.

As a result of the process improvement discussions, EPA is making two significant changes to its registration review process: 1) hold "Focus" meetings at the start of the registration review for each active ingredient, and 2) consult informally with the Services early in the review process and initiate any needed formal consultations at a subsequent stage. Figure 2 outlines EPA's revised registration review process.

Figure 2. Revised Design for EPA's Registration Review Process



One major end result of these process changes is that through public involvement, particularly with growers who are responsible for "on the ground" implementation of pesticide product label language, risk reduction measures that achieve protection for listed species and designated critical habitat and that are technologically and economically feasible can be achieved, possibly through changes to labels, or via species' bulletins[10]. The involvement of growers and state lead agencies will also ensure that the protection measures are economically and technologically feasible.

[10] More on EPA's Bulletins Live! can be found at http://www.epa.gov/oppfead1/endanger/bulletins.htm

4 Services' ESA Consultation Process

Under the Services' ESA regulations[11], when a Federal agency determines that its proposed action may adversely affect a listed species or critical habitat, the agency is obligated to enter into formal consultation with the Services to ensure that the action is not likely to result in jeopardy to the listed Species, or destroy and/or adversely modify critical habitat.

However, before initiating formal consultation under section 7 of the ESA, a Federal agency, or a designated non-Federal representative can consult "informally."[12] Informal consultation is an optional process that can be used to (1) clarify whether and what listed, proposed and candidate species, or designated, or proposed critical habitat may be in the action area; (2) determine what effect the action may have on these species and critical habitat; (3) explore ways to modify the action to reduce or remove adverse effects to the species and critical habitat; (4) determine the need to enter into formal consultation; and (5) explore modifications of an action to benefit listed species. Participants in informal consultation may include the (1) Federal action agency, (2) applicant, (3) non-Federal representative, or (4) consultant working on behalf of one of the first three. There is no overall timetable for informal discussions, and dialogue can continue as long as the parties are willing to participate and are actively working to complete the consultation. If during informal consultation the Federal agency determines, with written concurrence of the Services, that the action is not likely to adversely affect listed species or critical habitat, the consultation process is terminated.

When EPA determines that formal consultation with one or both of the Services is necessary, continued engagement with registrants and interested stakeholders (e.g., growers, state agencies, conservation groups, and water quality groups) is vital. Under ESA regulations, registrants are considered "applicants." Applicants have certain defined opportunities under the regulations, including the opportunity to submit information during the consultation and review draft biological opinions.

Upon receiving a request to initiate formal consultation from EPA, the Service will convene a meeting with EPA and the applicant to identify what additional information – beyond that provided by EPA in its package initiating consultation – can be provided for consultation and subsequent drafting of the biological opinion. To ensure that all agency expertise is involved, EPA will extend an invitation to USDA to attend the applicant meetings. During consultation, the Services may discuss with EPA its risk assessment and effects determination to gain a better understanding and they may seek out additional information from other sources. If the Services believe that changes to the pesticide label may be necessary to avoid or reduce the extent of adverse effects to listed species or critical habitat, they will work with EPA and USDA to engage the applicant, product users, and other stakeholders to discuss possible label changes needed to avoid jeopardizing the continued existence of listed species and destroying or adversely modifying critical habitat. Before analyzing the effects of the action, the Services, EPA, and applicants will review and agree upon the description of the action (e.g., use rates, registered uses, scope of the proposed action as described on pesticide labels).

The Services will prepare draft biological opinions that include their analyses and conclusions regarding whether use of the pesticide is likely to jeopardize the continued existence of a federally-listed

[11] See 50 CFR Part 402.
[12] Endangered Species Consultation Handbook, USFWS and NMFS March 1998; 50 CFR 402.13

species or to destroy or adversely modify critical habitat under their purview. If FWS and/or NMFS determine that jeopardy or adverse modification of critical habitat is likely, they are obligated to work with EPA and the applicant to identify Reasonable and Prudent Alternatives (RPAs), to the extent such measures exist, to insure that the action will avoid the likelihood of jeopardizing listed species or destroying or adversely modifying critical habitat. Service regulations require that these are measures that can be implemented in a manner consistent with the intended purpose of the action, can be implemented within the scope of EPA's legal authority and jurisdiction, and are economically and technologically feasible. Where the Services anticipate "take"[13] of listed species, the draft biological opinion(s) includes proposed Reasonable and Prudent Measures (RPMs) and terms and conditions to minimize the impact of the take.

The Services will provide EPA with the draft biological opinion for their review. EPA will make the draft biological opinion available for public comment. The public comment period provides another opportunity for stakeholders to provide valuable input on RPAs, RPMs, and terms and conditions, as well as to provide/suggest/propose alternate risk reduction measures that accomplish the same protection goals but may be easier/less costly for the grower/user community to implement. All comments will be submitted to EPA, although the applicant may send a copy of its comments directly to the Service. EPA will organize the comments and highlight those of particular note and provide them to the Services.

During the public comment period, EPA and the Services, supported by USDA, will solicit input from growers and other stakeholders on any technologically and economically feasible approaches that minimize the impact on growers and that allow them to meet their pest control needs while achieving the necessary protection goals to avoid jeopardy to threatened and/or endangered species. In particular, this process should offer stakeholders an opportunity to provide data and to identify practical considerations that affect the viability of different options for mitigating risks to species. EPA will provide a key role by focusing affected entities on the availability of the draft biological opinion and timeframes for submission of input.

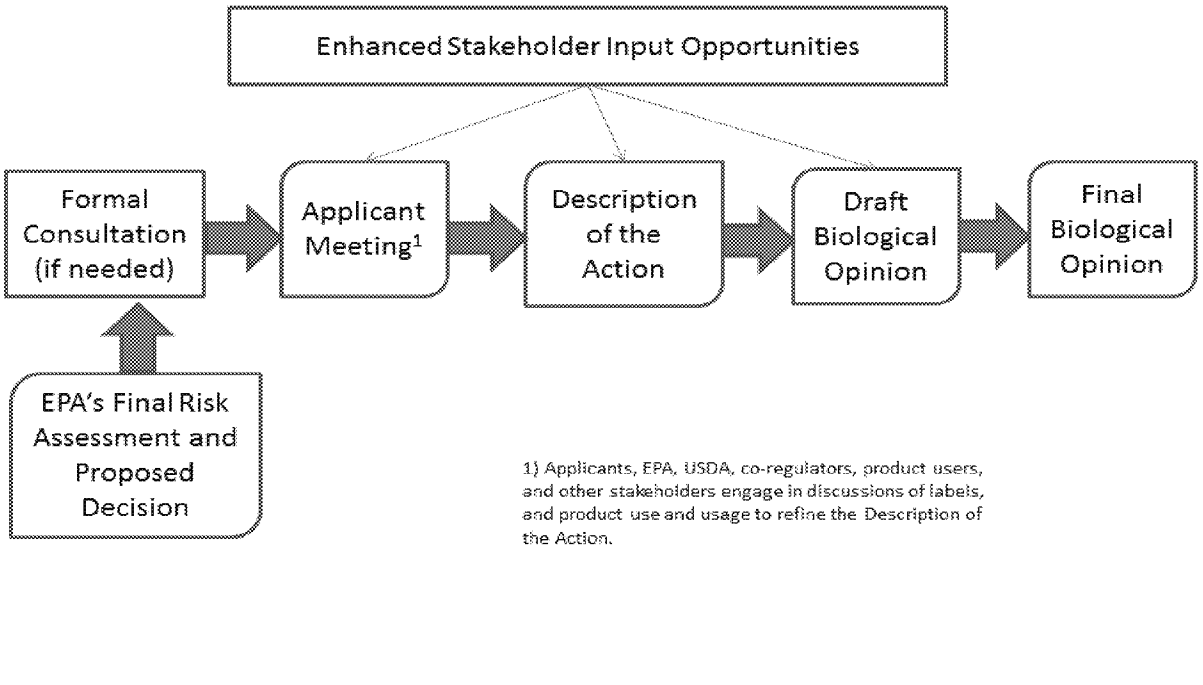
Upon receipt of the organized public comments from EPA, each Service will prepare a document for their respective opinions, where applicable, and include it in the administrative record that addresses how comments were considered and, if appropriate, how the final document was modified to address the comments. Each Service will include this document in their respective administrative records and will provide it to EPA. Both the Services and EPA will make the document available to the public upon request.

The ESA and section 7 regulations require that formal consultation be concluded within 90 calendar days of initiation, and that the biological opinion be delivered to the action agency within 45 days of the conclusion of formal consultation, unless an extension is agreed to by the agencies and any applicant. EPA will seek an extension to the consultation process when they determine that the statutory timeframes fail to provide adequate time for consideration of information obtained through this process. However, if the extension exceeds more than 60 days, i.e., 150 days from initiation of formal consultation, EPA and the Services must seek consent from the applicants. It should be recognized, however, that circumstances beyond the government's control (e.g., the refusal of an applicant to agree to an extension) may force the process described above to be more truncated.

[13] Take – to pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to pursue, hunt, wound, kill, trap, capture, or collect. See 50 CFR§10.12.

Throughout the consultation, it is critical that the established expertise of each agency is recognized and respected: the Services are the expert agencies regarding the species; EPA is the expert agency on pesticide risk assessment, regulation, and the enforceability of labels. USDA will lend its expertise on farming/pest management practices and the technological or economic feasibility of adopting potential risk reduction strategies. Therefore, in developing draft RPAs and RPMs, the Services should include only those risk reduction measures that EPA has the authority to impose and should then defer to EPA to implement these measures using its existing statutory authorities. For example, the Services might identify a level of exposure below which jeopardy would not occur. In response, EPA will implement changes to the pesticide registration that will reasonably ensure that the specified level of exposure is not exceeded. Figure 3 outlines the Service's formal consultation process.

Figure 3. Services' Formal Consultation Process



5 Conclusion

In summary, the Services, EPA, and USDA intend that these changes will result in greater openness and transparency in the pesticide registration review process under FIFRA and in the consultation process under the ESA. Consistent with the statutory mandate to use the best available information, the goal of these changes is to improve stakeholder involvement in these processes and to improve the respective agencies' understanding of how pesticides are used, the ways in which they may affect listed species, and how risks to listed species can be mitigated while preserving the beneficial uses of the pesticides to the extent possible.